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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,354	06/30/2004	Masayo Higashiyama	2004_1016A	2612
	7590 08/05/2008	EXAMINER		
WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021			RAE, CHARLESWORTH E	
			ART UNIT	PAPER NUMBER
	,		1611	
			MAIL DATE	DELIVERY MODE
			08/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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	Application No.	Applicant(s)				
Office Action Democratic	10/500,354	HIGASHIYAMA, MASAYO				
Office Action Summary	Examiner	Art Unit				
	CHARLESWORTH RAE	1611				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
 A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). 						
Status						
1) Responsive to communication(s) filed on <u>08 Ma</u>	a <u>y 2008</u> .					
2a)⊠ This action is FINAL . 2b)∏ This)∑ This action is FINAL . 2b)□ This action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
 4) Claim(s) <u>1-11</u> is/are pending in the application. 4a) Of the above claim(s) <u>11</u> is/are withdrawn from consideration. 5) Claim(s)						
Application Papers						
 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. 						
Priority under 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date U.S. Patent and Trademark Office PTOL-326 (Rev. 08-06)	4) ☐ Interview Summary Paper No(s)/Mail Da 5) ☐ Notice of Informal P 6) ☐ Other: tion Summary Pa	ate				

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DETAILED ACTION

Acknowledgement is made of applicants' filing of the instant application as a

Request for Continued Examination (RCE) under 37 CFR 1.1114.

Applicant's statement that support for the claim amendment may be found in the

specification at page 8, lines 8-15, is acknowledged.

Status of the Claims

Claims 1-11 are currently pending in this application.

Claim 11 is withdrawn for examination purposes for being directed to non-elected

subject matter.

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Claim 1-10 are currently under examination.

Amendment

Claims 1 and 10 have been amended to specify that the metal chloride is a light-stabilizing agent.

Miscellaneous Comments

Applicant's request for a personal interview prior to this Office action is

acknowledged. However, the examiner made several attempts to schedule an interview

with applicant without any success. In view of the inability to schedule a timely

interview, this Office action is being issued.

Claim rejections – 35 USC 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 are rejected under 103(a) as being unpatentable over Koida et al. (JP 2001261553A, abstract only; already made of record), in view of Kita et al (US Patent 6,307,052 B1; already made of record), and Remington's (Remington's Pharmaceutical Sciences. 1980; pages 1410-1419; already made of record).

It is noted that the light-stabilizing effect of the metal chloride salts encompassed by the instant claims is deem to be a characteristic that is inseparable from the chemical entity such that the light-stabilizing effect of said metal chloride salts is deemed to be coextensive with the claimed aqueous liquid preparation. Thus, the amendment of claims 1 and 10 to recite the light-stabilizing limitation does not confer patentability to the applicant's claimed invention.

Koida et al. teach bepotastine (i.e. (S)-4-[4-[(4-chlorophenyl)(2pyridyl)methoxy]piperidino] butyric acid) has optical purity and has markedly improved

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storage stability because of no occurrence of racemization (abstract). Claims 1, 4, 5, and 10 recite said compound.

Koida et al. do not teach applicant's instant claimed aqueous liquid preparation comprising bepotastine and a water-soluble metal chloride.

Kita et al. is added to show the general state of the art regarding aqueous preparations comprising benzenesulfonate and a compound containing a 2-pyridyl moiety having antihistaminic activity. Kita et al. teach that the benzenesulfonate and benzoate of (S)-4-[4-[(4-chlorophenyl)(2-pyridyl)methoxy]piperidino]butanoic acid possesses excellent antihistaminic and antiallergic agent activity (column 1, line 10 to column 3, line 19). Kita et al. teach that the acid addition salt has little hydroscopicity and excellent physiochemical stability so that it is a particularly suitable compound as a medicine for allergic skin diseases, allergic rhinitis, sneeze, mucus, cough due to respiratory inflammation such as a cold, and bronchial asthma (column 1, lines11-54).

Remington's Pharmaceutical Sciences (1980) is added to show the general state of the art regarding the utilization of metal chlorides in aqueous pharmaceutical preparations such as eye and nasal drops. Remington's teaches <u>sodium chloride</u> <u>equivalents of certain medicinals in aqueous solution</u> (pages 1411, column 2, to 1419; Appendix A; page 1419, Appendix B), which includes **calcium chloride** (page 1413), **potassium chloride** (page 1417), **sodium chloride** (page 1418), **benzalkonium chloride** (page 1413). Remington's teaches that besides water, certain other solvents are frequently employed in **nose drops**, ear drops, and other preparations to be used in various parts of the body (page 1410, column 2, second paragraph from the bottom).

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